

## CLAIMS

1. A method of diagnosing bone metastasis of malignant tumor using a marker that reflects the activity of osteoblasts and a marker that reflects the action of osteoclasts.

2. The method according to claim 1, wherein the marker that reflects the activity of osteoblasts is:

- (1) a marker associated with the phase of osteoblast proliferation and matrix formation and a marker associated with the phase of calcification; or
- (2) a marker associated with the phase of matrix maturation and a marker associated with the phase of calcification.

3. The method according to claim 1 or 2, wherein the marker that reflects the activity of osteoblasts is:

- (1) PICP or PINP and osteocalcin; or
- (2) BALP and osteocalcin.

4. The method according to any one of claims 1-3, wherein the marker that reflects the action of osteoclasts is a marker associated with bone type I collagen.

5. The method according to any one of claims 1-4, wherein the marker that reflects the action of osteoclasts is deoxypyridinoline and/or ICTP.

6. The method according to any one of claims 1-5, which is based on the value of a crossover index or the ratio between a marker associated with the phase of calcification and a marker associated with the phase of osteoblast proliferation and matrix formation and the measured value of the marker that reflects the action of

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osteoclasts, or on the value of a crossover index or the ratio between a marker associated with the phase of calcification and a marker associated with the phase of matrix maturation and the measured value of a marker associated with bone type I collagen.

7. The method according to claim 6, which is based on the value of a crossover index between osteocalcin and PICP or PINP and the measured value of ICTP, or on the value of a crossover index between osteocalcin and BALP and the measured value of ICTP.

8. A method of evaluating the therapeutic efficacy of a drug using a marker that reflects the activity of osteoblasts and a marker that reflects the action of osteoclasts.

9. The method according to claim 8, wherein the drug is a cancer control therapeutic agent.

10. The method according to claim 8, wherein the drug is a bone resorption suppressant.

11. The method according to claim 8, wherein the drug is an endocrine therapeutic agent.

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12. The method according to any one of <sup>claim 8</sup> claims 8 - 11, wherein the marker that reflects the activity of osteoblasts is:

- (1) a marker associated with the phase of osteoblast proliferation and matrix formation and a marker associated with the phase of calcification; or
- (2) a marker associated with the phase of matrix maturation and a marker associated with the phase of calcification.

claim 8

13. The method according to ~~any one of claims 8 or 12~~, wherein the marker that reflects the activity of osteoblasts is:

(1) PICP or PINP and osteocalcin; or

(2) BALP and osteocalcin.

claim 8

14. The method according to ~~any one of claims 8 - 13~~, wherein the marker that reflects the action of osteoclasts is a marker associated with bone type I collagen.

claim 8

15. The method according to ~~any one of claims 8 - 14~~, wherein the marker that reflects the action of osteoclasts is deoxypyridinoline and/or ICTP.

claim 8

16. The method according to ~~any one of claims 8 - 15~~, which is based on the value of a crossover index or the ratio between a marker associated with the phase of calcification and a marker associated with the phase of osteoblast proliferation and matrix formation and the measured value of the marker that reflects the action of osteoclasts, or on the value of a crossover index or the ratio between a marker associated with the phase of calcification and a marker associated with the phase of matrix maturation and the measured value of a marker associated with bone type I collagen.

17. The method according to ~~claim 16~~, which is based on the value of a crossover index between osteocalcin and PICP or PINP and the measured value of ICTP, or on the value of a crossover index between osteocalcin and BALP and the measured value of ICTP.